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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,176	06/14/2007	Shuji Hayashi	50026/063001	5427

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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02/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/599,176	Applicant(s) HAYASHI ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 17-19, 25 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13, 15, 17-19, 25 and 32-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding HGF.

Group II, claim(s) 1-4,6,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding FGF2.

Group III, claim(s) 1-4,7-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding IFN.

Group IV, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding VEGF.

Group V, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding PDGF.

Group VI, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding interleukin.

Group VII, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding GCSF.

Group VIII, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding MCSF.

Group IX, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding SCF.

Group X, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding Crx.

Group XI, claim(s) 1-4,8-13,15,17-19,25, drawn to a bone marrow related cell transformed with a vector comprising a gene encoding Otx2.

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Group XII, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding HGF.

Group XIII, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding FGF2.

Group XIV, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding IFN.

Group XV, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding VEGF.

Group XVI, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding PDGF.

Group XVII, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding interleukin.

Group XVIII, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding GCSF.

Group XIX, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding MCSF.

Group XX, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding SCF.

Group XXI, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding Crx.

Group XXII, claim(s) 32-38, drawn to a method of maintaining or repairing a tissue using bone marrow related cells transformed with a vector comprising a gene encoding Otx2.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.

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3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The only technical feature linking the inventions is a transformed bone marrow-related cell, which is not a contribution over the prior art (see Studeny, 2002, Cancer Research, Vol.62, pages 3603-3608). Studeny taught bone marrow-derived mesenchymal stem cells transformed with a gene encoding IFN.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in

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scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/
Primary Examiner, Art Unit 1632

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